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10/553,973	10/19/2005	Gianluca Gazza	5719	8204
26936	7590	06/09/2009	EXAMINER	
SHOEMAKER AND MATTARE, LTD			DORNBUSCH, DIANNE	
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SILVER SPRING, MD 20910			ART UNIT	PAPER NUMBER
			3773	
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			06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/553,973	GAZZA, GIANLUCA	
	<b>Examiner</b>	<b>Art Unit</b>	
	DIANNE DORNBUSCH	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 March 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 72-142 is/are pending in the application.  
 4a) Of the above claim(s) 102-104, 106-112 and 115-142 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 72-101, 105, 113 and 114 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 19 October 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Specification***

1. The disclosure is objected to because of the following informalities: on page 3 lines 15-19 claims 1 and 34 are referred to but they no longer exist.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 72-101, 105, 113, and 114 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 72, 101, and 105 state "in order to deploy the balloon in all the radial directions", the original disclosure does not state this reasoning therefore it is considered new matter.

For purposes of this action this statement will not be considered during the prior art examination.

In addition, independent claims 72, 101, and 105 state "the wall cavity following the balloon structure outline at least following the proximal shank and the distal shank." The original disclosure shows that wall cavity following the balloon structure outline in

the drawing, however the original disclosure does not state that the wall cavity follows at least the proximal and distal shanks; hence this is considered new matter.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 72-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 72 and 101 have the limitations "an annular cross-section" which is first introduced in paragraph 5 of the claims and later is reintroduced in paragraph 8 of the claims. It is unclear to the examiner if the applicant is referring to two different annular cross-sections or the same one.

#### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

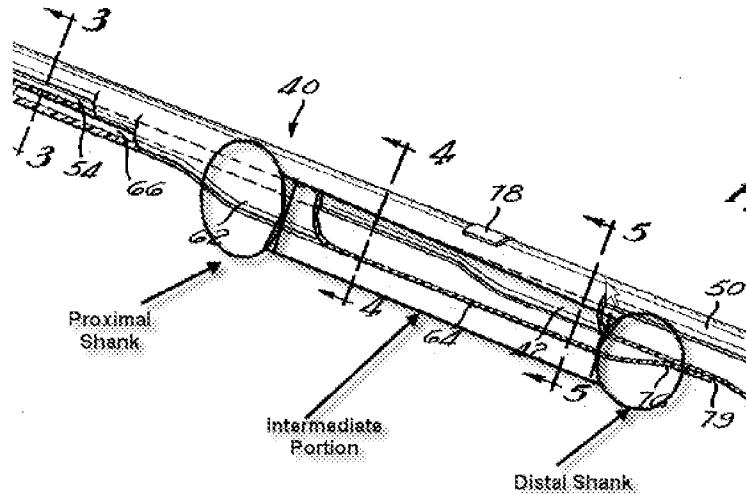
7. Claims 72-79, 81, 83-86, 100, 101, 105, 113, and 114 are rejected under 35 U.S.C. 102(b) as being anticipated by Jang (4,958,634).

Jang discloses the following claimed limitations:

Claims 72, 101, and 105: An inflatable balloon structure (62) for catheters comprising a proximal shank (see figure below), a distal shank (see figure below), and an intermediate portion (where the cross sections 4 and 5 are taken in Fig. 2, see figure

below) between the proximal and distal shanks (see figure below); said balloon structure when the inflation chamber is expanded, has an outer surface of a circular cross-section transverse to the longitudinal extent of the balloon structure (Fig. 4-5 where it can be seen that the balloon has a circular cross-section); the balloon structure comprising a wall (64, 70, 72) which has, transverse the longitudinal extent, at any point (Fig. 1-5), an annular cross-section (Fig. 4-5), said annular cross-section being delimited externally by an outer surface (outer surface of wall 64) (Fig. 4-5) which, at least in the intermediate portion (where the cross sections 4 and 5 are taken in Fig. 2) thereof, is suitable for coming into contact with the object to be dilated (when inflated the outer surface will dilate the vessel wall), and said annular cross-section being delimited internally by an inner surface (52, 56) which delimits an inflation chamber (66), in which: at least one wall cavity (54) is provided in the wall and is formed within an annular cross-section (Fig. 4) which delimits the inflation chamber so as to be disposed between the outer surface and the inner surface the wall cavity extending, without interruptions and/or openings, longitudinally relative to the balloon structure between the proximal end and the distal end so that (fig. 3-5 and Col. 11 Lines 63-64), when the balloon structure is inflated or expanded, the outer surface of the intermediate portion has, in cross-section transverse the longitudinal extent of the balloon structure, uniform curvature around the entire annular extent of the cross-section (Fig. 4-5); the wall cavity following the balloon structure outline at least following the proximal shank and the distal shank (Fig. 1 where it can be seen that the wall cavity has the same outline as the balloon structure however they are not in face with each other).

Note that applicant does not state that the outline has to be in face with each other therefore Jang does show the outline as claimed.



Claim 73: That the balloon structure is inflated or expanded, the outer surface of the intermediate portion is free of protuberances or recesses (Fig. 4-5).

Claim 74: That the wall cavity is within the wall which delimits the inflation chamber for the whole of its extent which affects the balloon structure (Fig. 4-5).

Claim 75: That the balloon structure is inflated or expanded, the outer surface of the intermediate portion is cylindrical (fig. 4-5).

Claim 76: When the inflation chamber is expanded, the balloon structure has an annular cross-section of the outer surface, transverse the longitudinal extent of the balloon structure (Fig. 4-5 and Col. 11 Lines 63-64).

Claim 77: When the inflation chamber is expanded, the balloon structure has a substantially circular cross-section of the outer surface, transverse the longitudinal extent of the balloon structure (Fig. 4-5 and Col. 11 Lines 63-64).

Claim 78: That the balloon comprises a proximal tubular portion (50) in the vicinity of the proximal end (Fig. 2-3 where the proximal end is where the cross section 3 is taken in Fig. 2).

Claim 79: That the balloon comprises a proximal shank (the tapered area at the proximal end where the balloon tapers to attach to 50) connecting the proximal tubular portion (50) and an intermediate portion (Fig. 2).

Claim 81: That the balloon comprises a distal connecting shank (the tapered portion of the balloon near where part 76 is labeled in Fig. 2) between the intermediate portion and a portion for connection to a distal catheter tip (combination of part 79 to 74).

Claim 83: That the wall cavity is separated from the inflation chamber by an internal portion of the wall (52, 56).

Claim 84: That the cavity is separated from the outer surface by an external portion of the wall (portion 72).

Claim 85: When the balloon structure is inflated or expanded, the inner surface of the intermediate portion is smoothed, rounded, or free of sharp corners (Fig. 4-5).

Claim 86: When the balloon structure is inflated or expanded, the inner surface of the intermediate portion has an annular cross-section, transverse the longitudinal extent of the balloon (Fig. 4-5).

Claim 100: That the inflation chamber is closed in a leak tight manner (there cannot be any leaks since it would cause the balloon to not completely inflate) onto an apex tip (Fig. 2), leaving solely openings for access to one or more guide-wire cavities (60).

Claim 113: That the wall portion which separates the wall cavity from the outer surface has an opening (60) which forms a lateral aperture for allowing a guide wire to be inserted in the wall cavity or to emerge therefrom (Col. 11 Line 33).

Claim 114: That the balloon structure is connected proximally to a shaft (50) comprising an inflation cavity (the proximal end of 66) connected to the inflation chamber in a leak tight manner for the flow of a fluid from the shaft to the inflation chamber and vice versa (Fig. 2) (there cannot be any leaks since it would cause the balloon to not completely inflate).

8. Claims 87, 88, 91-95, and 97 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jang (4,958,634).

Claim 87:

Jang discloses that the structure is produced from an extruded tube having at least two cavities, one of which is deformed to form the inflation chamber of the balloon structure (Col. 19 Lines 15-20).

Furthermore, the examiner would like to note that the claimed phrase, "produced from an extruded tube having at least two cavities", is a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Claim 88:

Jang teaches that the balloon structure comprises an extruded tube (Col. 19 Lines 15-20), but is silent as to the extruded tube having a partially flat partition separating the cavities prior to the deformation of the cavities (after deforming the cavity the final product is obtained). The claimed phrase “that prior to the deformation of a cavity of the extruded tube to form an inflation chamber, the extruded tube has an at least partially flat partition separating the at least two cavities” is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Jang is silent as to the structure of the device prior to the deformation of the cavity which will lead to the final product, it appears that the product in Jang would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made of an extruded tube.

Claims 91-95 and 97:

Jang teaches that the balloon structure comprises an extruded tube (Col. 19 Lines 15-20) with at least two cavities (Fig. 4); the tube having two to three materials (each wall that surrounds a lumen in Fig. 4 is a material); that the material that delimits the inflation cavity is a material that is semi-compliant (since the this material is the outer wall of the balloon it is compliant in order to allow the balloon to inflate to a maximum point (Col. 19 Line 15)); that the balloon structure is produced by the

expansion of an inflation cavity of a tube with at least two cavities (Col. 19 Lines 62-66), that the second material forms the wall portion which separates the wall cavity from the outer surface (Fig. 4) and has a greater flexibility than the first material (if the first material is the material that delimits the inflation cavity, then when the balloon is inflated it reaches a maximum where it is not as flexible as the second material).

Jang teaches all the limitations discussed above but is silent as to the co-extruding methods. The claimed phrases the method of producing the balloon structure through a co-extruded tube is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Jang is silent as to the co-extruding methods, it appears that the product in Jang would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made of an extruded tube.

#### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 80, 82, 89, 90, 98, and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jang (4,958,634).

Claims 80 and 82:

Jang discloses the claimed invention except for the internal taper angle of the proximal and distal shank ranges from 20-40 degrees, preferably 30 degree. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a tapered angle between 20 to 40 degree, preferably 30 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 89 and 90:

Jang teaches that the balloon structure comprises an extruded tube (Col. 19 Lines 15-20), but is silent as to the configuration of the extruded tube prior to the deformation of the cavities (after deforming the cavity the final product is obtained). The claimed phrase “ prior to the deformation of a cavity of the extruded tube to form an inflation chamber, the extruded tube has a partition separating the at least two cavities which partition has, in cross-section transverse the extruded tube” is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Jang is silent as to the structure of the device prior to the deformation of the cavity which will lead to the final product, it appears that the product in Jang would be the same or similar as that claimed; especially since both applicant's product and the prior art product is made of an extruded tube.

Furthermore, Jang discloses the claimed invention except for the minimum thickness of the partition separating the two cavities prior to deformation of the cavities being between 55% and 100% (claim 89) or between 60% and 70% (claim 90) of the minimum thickness of the wall. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the partition to be a minimum thickness between 55% and 100% or 60% and 70% of the minimum thickness of the wall, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 98 and 99:

Jang discloses the claimed invention (Fig. 2-5) except for the thickness of the wall portion separating the wall cavity and the inflation chamber when the balloon structure is inflated/expanded is between 55% and 100% (claim 98) or between 60% and 70% (claim 99) of the thickness of the wall portion that separates the wall cavity from the outer surface. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the wall portion separating the wall cavity and the inflation chamber to have a thickness between 55% and 100% or 60% and 70% of the of the wall portion that separates the wall cavity from the outer surface, since it

has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jang (4,958,634) in view of Werneth et al. (6,576,001).

Jang teaches all the claimed limitations discussed above however, Jang does not disclose that the wall cavity is coated with or delimited by a layer of material with a coefficient of friction such as to facilitate the sliding of a guide wire housed in the wall cavity.

Wernerth discloses that the wall cavity (424) is coated with or delimited by a layer of material (lubricous coating) with a coefficient of friction such as to facilitate the sliding of a guide wire housed in the wall cavity (Col. 25 Lines 38-41).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Jang with a lubricous coating in view of the teachings of Werneth, in order to facilitate the sliding of the catheter over the guidewire (Col. 25 Lines 38-41).

### ***Response to Arguments***

12. Applicant's arguments filed March 31, 2009 have been fully considered but they are not persuasive.

Applicant argues that the Jang does not disclose a cavity wall that follows the outline of the balloon structure. The examiner disagrees, as explained in the rejection above, the wall cavity of Jang does have the same outline as the balloon structure

including the proximal and distal shank portions, however, the outline of the wall cavity of Jang is not in face with the balloon structure. Since applicant did not specify that the outline had to be in infac or out of face, the examiner interpreted it as being out of face.

Furthermore, applicant argues that the balloon disclosed by Jang does not deploy the balloon uniformly in all the radial directions. This statement was rejected under 35 U.S.C. 112 1st paragraph, due to the statement being new matter. Due to this rejection, the statement was not examined. However, the Jang reference does disclose that the balloon is expanded uniformly in all its radial directions, since as air flows into the balloon it will uniformly inflate the balloon (Col. 4 Lines 53-56).

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./  
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/  
Supervisory Patent Examiner, Art Unit 3773